

Remarks

Claims 1-3 are pending in the application. Claims 1-3 stand rejected under 35 U.S.C. 102(e). The present Response amends claim 1. The rejection raised in the Office Action is addressed below.

Rejection Under 35 U.S.C. §102(e)

Claims 1-3 stand rejected as being anticipated by Broeckaert et al. (U.S. Patent No. 5,824,869). The Examiner stated that in view that Broeckaert et al. disclose of a nucleic acid encoding a non-mammalian anti-microbial protein, which has been altered by one or more alterations compared to the natural host, and that the protein was secreted in its active form, the DNA disclosed by Broeckaert et al. is deemed to anticipate the claimed invention. Applicant disagrees.

Claim 1 now recites a nucleic acid comprising a modified gene encoding a non-mammalian *anti-staphylococcal* protein, the gene including a sequence that codes for an amino acid sequence that is identical to the anti-microbial protein produced by the natural host except that the coding sequence includes one or more alterations that disrupt one or more mammalian post-translational processing events so that the non-mammalian protein is produced and secreted by mammalian cells in its active form.

There is no disclosure in Broeckaert et al. of any gene encoding a protein having anti-staphylococcal activity. Although Broeckaert et al. disclose genes encoding proteins having anti-fungal and anti-microbial activity, there is no teaching of genes encoding proteins that have anti-staphylococcal activity.

Broekaert et al. disclose three classes of proteins isolated from the seeds of the members of the Brassicaceae, Compositae, or Leguminosae families. For example, a first class includes antifungal proteins (AFP) isolated from the seeds of *Raphanus sativus*, specifically Rs-AFP1 and Rs-AFP2 (column 2, lines 32-36). Another antifungal protein, *Raphanus sativus* non-specific lipid transfer protein (Rs-nsLTP), is isolated from radish seeds (column 3, lines 41-43). A second class of proteins includes anti-microbial proteins (AMP) isolated from the seeds of Dahlia and Cnicus, specifically Dm-AMP1, Dm-AMP2, Cb-AMP1, and Cb-AMP2 (column 2, lines 42-48). Broekaert et al. disclose that the AMPs have antifungal activity and are also active against Gram positive bacteria (column 4, lines 31-33). However, there is no disclosure in Broekaert et al. of any protein having anti-staphylococcal activity, nor is any protein demonstrated to have anti-staphylococcal, or even anti-bacterial activity. Only anti-fungal activity is shown (see, e.g., Figures 1, 3, 7, 9, 11, 13, 16, and 18). Furthermore, the claims require that the anti-staphylococcal protein is produced and secreted by mammalian cells in its active form, in which regards the Broekaert et al. patent is completely lacking. Without such teachings, Broekaert et al. cannot anticipate the claims.

Anticipation under 35 U.S.C. 102 requires that the invention disclosed by the prior art reference must be identical to the claimed invention in each and every aspect. As stated in *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986), "[I]t is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention." Nowhere do Broekaert et al. disclose a gene encoding an anti-staphylococcal protein as presently claimed. Nor do Broekaert teach of an anti-staphylococcal protein produced and secreted in mammalian cells in its active form. Therefore, the Broekaert et

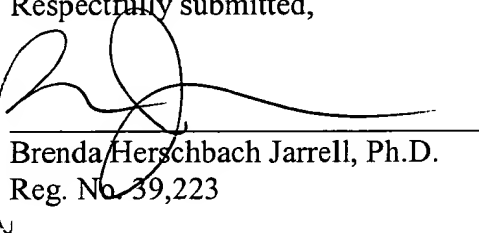
al. patent cannot anticipate the claimed invention and withdrawal of the rejection under 35

U.S.C. § 102(e) is respectfully requested.

Conclusion

Applicant respectfully requests entrance of the above Amendment and consideration of the above Remarks. Please charge any fees that may be required, or credit any overpayments, to our Deposit Account No. 03-1721.

Respectfully submitted,



Brenda Herschbach Jarrell, Ph.D.
Reg. No. 39,223

PATENT GROUP
CHOATE, HALL & STEWART
Exchange Place
53 State Street
Boston, MA 02109
Tel: (617) 248-5000
Fax: (617) 248-4000
Date: June 13, 2003